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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,088 | 07/26/2001 | Alessandro Lambiase | 36226/125733 | 6075 |

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| EXAMINER | |
|---|---|
| HAGOPIAN, CASEY SHEA | |
| ART UNIT | PAPER NUMBER |
| 1615 | |
| MAIL DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/890,088 | LAMBIASE, ALESSANDRO | |
| | Examiner | Art Unit | |
| | CASEY HAGOPIAN | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-15,17-21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17-21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination/Remarks filed 11/19/2007.

No amendments to the claims were submitted. Claims 13-15, 17-21, 23-36 are pending.

### MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 5/17/2007:

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 13-15, 17-21 and 23-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lambiase (WO 98/48002).**

Lambiase discloses methods of treating pathologies affecting the internal tissues of the eye by administering between 10 to 500 μg/ml of nerve growth factor to an individual (abstract and page 12, lines 14). The NGF can be administered either topically or over the ocular surface of an individual and treats corneal and/or conjunctival affects (page 12, line 31 – page 13, line 23). In another embodiment, the NGF may be administered by introduction into the anterior chamber of the eye (page

12, lines 17-20). Like the instant application, the NGF may be in the form of an ophthalmic solution or gel and may be administered via a bandage or medical contact lens (page 12, lines 10-13). The NGF medicament can be of human origin and can be used to treat disorders originating from laser treatment (Claim 9, 15).

It is the examiner's position that, inherently, the composition advanced by Lambiase, when applied to the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Lambiase composition and method are identical to the instant compositions and methods (that is, topically applying a composition comprising 10 to 500 μg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Lambiase anticipates the compositions enumerated in the instant claim set.

**Claims 13-15, 18-19, 21, 24-28 and 30-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Finkenaur et al. (EP 0312208 A1).**

Finkenaur discloses aqueous gel formulations comprising 1 to 500 μg/ml of a polypeptide growth factor, such as nerve growth factor (abstract; page 3, lines 25-48; page 4, line 9). Said nerve growth factor can be used for wound healing in the anterior chamber of the eye (abstract) as well as internal incisions and wounds (page 6, lines 9-11). Said wound healing composition can be delivered topically to an individual via a bandage (page 2, lines 41, 49-50), eye drops, salves, etc. (page 6, lines 4-5).

It is the examiner's position that, inherently, the composition advanced by Finkenaur, when applied to the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Finkenaur composition and method are identical to the instant compositions and methods (that is, topically applying a composition comprising 1 to 500 μg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Finkenaur anticipates the compositions enumerated in the instant claim set.

***Response to Arguments***

Applicant's arguments, submitted 11/19/2007, with regards to the rejections under 35 USC 102 have been carefully and fully considered but they are not persuasive. Applicant argues that neither Lambiase nor Finkenaur teach a method for treating a pathology affecting internal tissues of the eye, wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body and choroidea and that the teachings of the references do not render the claims anticipated by inherency. Applicant additionally submitted case law to support their position, i.e. Perricone v. Medicis Pharmaceutical Corp. In summary, the claims were drawn to methods of treating and preventing sunburn or sunburn damage. The reference, Pereira, taught a cosmetic composition for topical application. The Federal Circuit found that the claims drawn to the method of prevention were

anticipated by the reference, but the claims drawn to the method of treatment were not anticipated by the reference. The Federal Circuit explained that the methods of treating sunburn was considered a new use of a known composition and thus, was considered patentable subject matter. In response, it is respectfully submitted that the examiner disagrees with applicant's position. Both references, Lambiase and Finkenaur teach topically applying NGF in the claimed amounts to the ocular surface of the eye (see Rejections above). The references also teach treating internal tissues of the eye such as the anterior chamber of the eye. It is also noted that Lambiase refers to an article discussing topical administration of NGF in effectively treating retinal pathologies (page 6, line 30 – page 7, line 6). Thus, Lambiase also effectively teaches that it was known in the art that NGF could be applied topically in order to treat internal tissues, specifically, the retina. In regards to the case law submitted by applicant, it is respectfully submitted that the case law is not analogous to the current application. The claims were directed towards a particular condition, that is, sunburn whereas applicant's claims do not set forth any particular pathology just that the pathology affects internal tissues of the eye. Furthermore, Pereira is completely silent to treating sunburn or any other skin condition whereas Lambiase and Finkenaur both teach topically applying the claimed active agent in the claimed amounts for treating internal tissues of the eye. As discussed above, Lambiase even discusses an article that effectively teaches that it was known in the art that NGF could be applied topically in order to treat the particular internal tissue, the retina. In light of these teachings, Lambiase and Finkenaur are also treating the same patient population that applicant includes in their claims. Thus, for

these reasons, the case law that applicant submitted is considered to not be analogous. Applicant is directed to MPEP § 2112.02 where process of use claims are discussed. It is stated that a prior art device anticipates a claimed process if the device carries out the process during normal operation and new and unobvious uses of old structures and compositions may be patentable. It is also stated, "when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated." This is particularly applicable to applicant's claims. Applicant is claiming a method of treating a pathology affecting specific internal tissues of the eye by topically applying NGF, wherein the NGF passes through the external tissues of the eye to said internal tissues of the eye. The art teaches the same method steps utilizing the same composition as well as teaches treating internal tissues of the eye. The claimed limitation "said nerve growth factor passes through external tissues of the eye to said internal tissues" is considered a property of the composition and the limitation "treatment of a pathology affecting internal tissues" is considered the result. Thus, for these reasons the examiner maintains the position that applicant's claims are anticipated by the cited prior art. Therefore, the rejections under 35 USC 102 are maintained.

## ***Conclusion***

All claims have been rejected; no claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615